AMENDED CLAIMS

[Received by the International Bureau on 02 FEB 2004 (02.02.04) ; original claims 1 to 31, replaced by claims 1 to 36]

1. Pharmaceutical composition characterized by comprising:

(a) a therapeutic amount of the protease inhibitor [5S-(5R*,8R*,10R*,11R*)]-10 - hydroxy - 2 - methyl-5-(1-methylethyl)-1-[2-(1-methylethyl)- 4 - thiazolyl] - 3,6 - dioxo - 8,11 - bis (phenylmethyl) - 2,4,7,12-tetraazatridecan-13-oic acid 5-thiazolylmethyl ester (ritonavir);

(b) a mixture of alcoholic solvent and alcoholic co-solvent of C_2-C_4;

(c) a mixture of medium chain mono/diglycerides of C_8-C_{10};

(d) a pharmaceutical suitable surfactant;

(e) an antioxidant.

2. Pharmaceutical composition in accordance with claim 1, characterized by optionally comprising:

(a1) an emulsion stabilizer;

(b1) a polarity corrector.

3. Pharmaceutical composition in accordance with claim 1, characterized by employing the protease inhibitor [5S-(5R*,8R*,10R*,11R*)]-10 - hydroxy - 2 - methyl-5-(1-methylethyl)-1-[2-(1-methylethyl)- 4 - thiazolyl] - 3,6 - dioxo - 8,11 - bis (phenylmethyl) - 2,4,7,12-tetraazatridecan-13-oic acid 5-thiazolylmethyl ester (ritonavir) in a concentration ranging from 1.0% to 60% in weight of the final composition.

4. Pharmaceutical composition in accordance with claim 3, characterized by employing the protease inhibitor [5S-(5R*,8R*,10R*,11R*)]-10 - hydroxy - 2 - methyl-5-(1-methylethyl)-1-[2-(1-methylethyl)- 4 - thiazolyl] - 3,6 - dioxo - 8,11 - bis (phenylmethyl) - 2,4,7,12-tetraazatridecan-13-oic acid 5-thiazolylmethyl ester

(ritonavir) in a concentration ranging from 10% to 50% in weight of the final composition.

5. Pharmaceutical composition in accordance with claim 1, characterized by the alcoholic solvent is used in a concentration ranging from 5.0% to 20% in weight of the final composition.

6. Pharmaceutical composition in accordance with claim 5, characterized by the alcoholic solvent is used in a concentration ranging from 5.0% to 15% in weight of the final composition.

7. Pharmaceutical composition in accordance with claim 1, characterized by the alcoholic co-solvent is used in a concentration ranging from 5.0% to 20% in weight of the final composition.

8. Pharmaceutical composition in accordance with claim 7, characterized by the alcoholic co-solvent is used in a concentration ranging from 5.0% to 15% in weight of the final composition.

9. Pharmaceutical composition in accordance with claim 1, characterized by the alcoholic solvent and the alcoholic co-solvent are used in a concentration ranging from 10% to 40% in weight of the final composition.

10. Pharmaceutical composition in accordance with claim 9, characterized by the alcoholic solvent and the alcoholic co-solvent are used in a concentration ranging from 10% to 30% in weight of the final composition.

11. Pharmaceutical composition in accordance with claim 1, characterized by the medium chain mono/diglycerides mixture of C_8-C_{10} is used in a concentration ranging from 20% to 80% in weight of the final composition.

12. Pharmaceutical composition in accordance with claim 11, characterized by the medium chain mono/diglycerides

mixture of C_8-C_{10} is used in a concentration from 20% to 70% in weight of the final composition.

13. Pharmaceutical composition in accordance with claim 1, characterized by the surfactant is used in a concentration ranging from 0.1% to 20% in weight of the final composition.

14. Pharmaceutical composition in accordance with claim 1, characterized by the antioxidant is used in a concentration ranging from 0.001% to 2.0% in weight of the final composition.

15. Pharmaceutical composition in accordance with claim 1, characterized by the alcoholic solvent is ethanol and the alcoholic co-solvent is propylene glycol.

16. Pharmaceutical composition in accordance with claim 1, characterized by the surfactant is polyethoxylated castor oil 35, and/or hydrogenated polyethoxylated castor oil 40, and/or polysorbates 20, 40, 60 or 80.

17. Pharmaceutical composition in accordance with claim 1, characterized by the antioxidant is butylated hydroxy toluene and/or alpha-tocopherol.

18. Pharmaceutical composition in accordance with claim 1 or 2, characterized by employing an emulsion-stabilizing agent in an concentration ranging from 0% to 60% in weight of the final composition.

19. Pharmaceutical composition in accordance with claim 1 or 2, characterized by the emulsion-stabilizing agent is polyethylene glycol 400 (PEG 400).

20. Pharmaceutical composition in accordance with claim 1 or 2, characterized by employing a polarity corrector agent in a concentration ranging from 0% to 0.5% in weight of the final composition.

21. Pharmaceutical composition in accordance with claim 1 or 2, characterized by the polarity corrector agent is citric acid and/or ascorbic acid.

22. Pharmaceutical composition in accordance with any one of claims 1-21, characterized by being employed for oral administration as an oral solution, hard gelatin capsules and/or soft gelatin capsules.

23. Pharmaceutical composition in accordance with claim 22, characterized by being employed for oral administration as soft gelatin capsules.

24. Pharmaceutical composition in accordance with any one of claims 1-21, characterized by being employed in the treatment of viral infections.

25. Pharmaceutical composition in accordance with any one of claims 1-21, characterized by being employed in medicine or veterinary.

26. Process for preparing soluble concentrate pharmaceutical compositions of [5S-(5R*,8R*,10R*,11R*)]-10 - hydroxy - 2 - methyl-5-(1-methylethyl)-1-[2-(1-methylethyl)- 4 - thyazolyl] - 3,6 - dioxo - 8,11 - bis (phenylmethyl) - 2,4,7,12-tetraazatridecan-13-oic acid 5-thiazolylmethyl ester (ritonavir), comprising the following steps:

(a2) dissolving [5S-(5R*,8R*,10R*,11R*)]-10 - hydroxy - 2 - methyl-5-(1-methylethyl)-1-[2-(1-methylethyl)- 4 - thiazolyl] - 3,6 - dioxo - 8,11 - bis (phenylmethyl) - 2,4,7,12-tetraazatridecan-13-oic acid 5-thiazolylmethyl ester (ritonavir), in a sufficient amount of an alcoholic solvent of C_2-C_4, under controlled temperature;

(b2) eliminating solid particles by filtration;

(c2) evaporating the alcoholic solvent, under reduced pressure at low temperature, to about half of its initial concentration;

(d2) adding an alcoholic co-solvent, a medium chain mono/diglycerides mixture, an antioxidant, an emulsion-stabilizing agent and a polarity corrector in the appropriate amounts for the composition;

(e2) removing the alcoholic solvent by distilling under reduced pressure until the remaining quantity is the desired quantity in the composition;

(f2) adding the surfactant under continuous stirring and keeping stirring until complete mixture;

(g2) correcting the composition final weight by adding the alcoholic solvent employed in the initial dissolution of ritonavir, if necessary.

27. Process in accordance with claim 26, characterized by the alcoholic solvent in (a2) is ethanol.

28. Process in accordance with claim 26, characterized by the step (a2) is conducted in a temperature ranging from 30°C to 45°C.

29. Process in accordance with claim 26, characterized by the step (c2) is conducted at a maximum temperature of 40°C.

30. Process in accordance with claim 26, characterized by the co-solvent is propylene glycol.

31. Process in accordance with claim 26, characterized by the medium chain mono/diglycerides mixture is a mixture of medium chain mono/diglycerides of C_8-C_{10}.

32. Process in accordance with claim 26, characterized by the antioxidant is butylated hydroxy toluene or alpha-tocopherol.

33. Process in accordance with claim 26, characterized by the emulsion-stabilizing agent is polyethylene glycol 400 (PEG 400).

34. Process in accordance with claim 26, characterized by the polarity corrector is citric acid or ascorbic acid.

35. Process in accordance with claim 26, characterized by the surfactant is polyethoxylated castor oil 35, and/or polyethoxylated hydrogenated castor oil 40, and/or polysorbates 20, 40, 60 or 80.

36. Process in accordance with claim 26, characterized by being employed in the preparation of concentrated pharmaceutical compositions of ritonavir for oral administration.